

**Claim Amendments**

(Marked Up Copy)

Please cancel Claims 1-20.

Please add the following new claims.

21. (New) A transdermal delivery device for diagnosing infectious disease comprising an antigen composition and an antigen composition holding portion, wherein the antigen composition is contained in the holding portion for transdermal delivery of the antigen wherein the device is in contact with the skin.

22. (New) The device of Claim 21, wherein the antigen composition holding portion comprises a material selected from the group consisting of medical tape, medical plaster, gauze, a patch and a patch band.

23. (New) The device of Claim 21, wherein the antigen composition comprises an antigen and a physiologically effective solution, wherein said physiologically effective solution promotes delivery of the antigen.

24. (New) The device of Claim 23, wherein the antigen is derived from a mycobacterial species selected from the group consisting of *Mycobacterium tuberculosis*, *Mycobacterium avium-intracellular*, *Mycobacterium kansaii*, *Mycobacterium fortuitum*, *Mycobacterium chelonae*, *Mycobacterium leprae*, *Mycobacterium africanum*, and *Mycobacterium microti*.

25. (New) The device of Claim 23 wherein the antigen comprises a mycobacterial antigen.

26. (New) The device of Claim 23, wherein the antigen is mycobacterial antigen selected from the group consisting of MPB44, MPB45, MPB51, MPB59, MPB64, MPB70, MPB80 and MPB83.

27. (New) The device of Claim 23, wherein the antigen comprises MPB64 and the physiologically effective solution comprises phosphate buffered saline and a surfactant.

28. (New) The device of Claim 27, wherein the surfactant comprises a polyoxyethylene sorbitan derivative.

29. (New) The device of Claim 21, wherein the infectious disease comprises tuberculosis.

### Pending Claims

Following entry of this response, Claims 21-29 will be pending.

21. A transdermal delivery device for diagnosing infectious disease comprising an antigen composition and an antigen composition holding portion, wherein the antigen composition is contained in the holding portion for transdermal delivery of the antigen wherein the device is in contact with the skin.

22. The device of Claim 21, wherein the antigen composition holding portion comprises a material selected from the group consisting of medical tape, medical plaster, gauze, a patch and a patch band.

23. The device of Claim 21, wherein the antigen composition comprises an antigen and a physiologically effective solution, wherein said physiologically effective solution promotes delivery of the antigen.

24. The device of Claim 23, wherein the antigen is derived from a mycobacterial species selected from the group consisting of *Mycobacterium tuberculosis*, *Mycobacterium avium-intracellular*, *Mycobacterium kansaii*, *Mycobacterium fortuitum*, *Mycobacterium chelonae*, *Mycobacterium leprae*, *Mycobacterium africanum*, and *Mycobacterium microti*.

25. The device of Claim 23 wherein the antigen comprises a mycobacterial antigen.

26. The device of Claim 23, wherein the antigen is mycobacterial antigen selected from the group consisting of MPB44, MPB45, MPB51, MPB59, MPB64, MPB70, MPB80 and MPB83.

27. The device of Claim 23, wherein the antigen comprises MPB64 and the physiologically effective solution comprises phosphate buffered saline and a surfactant.

28. The device of Claim 27, wherein the surfactant comprises a polyoxyethylene sorbitan derivative.

29. The device of Claim 21, wherein the infectious disease comprises tuberculosis.

## REMARKS

The present application is directed to devices and compositions for detecting and diagnosing infectious diseases. In particular, the application relates to the use of a transdermal delivery device to diagnose infectious diseases such as mycobacterial infections. Prior to the issuance of the August 27, 2002 office action, Claims 1-20 were pending. In an effort to facilitate prosecution Claims 1-20 have been canceled and Applicants retain the right to pursue cancelled claims at a later time. Claims 21-29 have been added and support for the new claims can be found generally within the specification. No new matter has been added. Accordingly, following entry of the present amendment Claims 21-29 will be pending.

### *Election/Restriction*

In the Office Action dated August 27, 2002, the Examiner requested restriction of the application to one of the following inventions:

- I. Claims 1-8, drawn to transdermal delivery device, classified in class 424, subclass 1.33, for example.
- II. Claims 9-16, drawn to method of detecting active disease, classified in class 435, subclass 32, for example.
- III. Claims 17-20, drawn to immunogenic composition, classified in class 514, subclass 946, for example.

Applicant herein elects Group 1 with traverse. Applicant respectfully submits that the device claims of Group I are so intrinsically related to the method claims of Group II that a search of both groups would not be burdensome. Applicant further submits that the Inventions of Group I and III are also intrinsically related and that a search of all three groups would not be burdensome.

In the August 27, 2002 Office Action, the Examiner stated that Inventions I and II are related as process and apparatus for its practice. Specifically the Examiner stated that in this case, application of an immunogenic composition by a device could be performed by intradermal injection and that therefore, since the process as claimed could be practiced by another materially different apparatus or by hand, it could be shown that the inventions are distinct. Applicant respectfully submits that in this context Inventions I and II are so interrelated, one encompassing a transdermal delivery device and the other encompassing methods of detecting active disease using such a transdermal delivery device,

that a search of both Inventions would not be burdensome. In an effort to facilitate prosecution however, claims to directed to Invention II have been cancelled herein.

In the August 27, 2002 Office Action, the Examiner further stated that inventions in the relationship of Inventions I and III are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. In this particular case the Examiner stated that the subcombination as claimed does not require a topical application device and that the subcombination has a separate utility such as for use as a vaccine. Applicant respectfully traverses. Applicants respectfully submit that in this context Inventions I and III are so interrelated one encompassing a transdermal delivery device and the other encompassing a composition for detecting active disease using such a transdermal delivery device, that a search of both Inventions would not be burdensome. In an effort to facilitate prosecution however, claims to directed to Invention III have been cancelled herein.

Also in the August 27, 2002 Office Action, the Examiner stated that Inventions II and III are related as product and process of use. According to the Examiner, since the antigen and physiologically active solution can be used in an assay for determining binding kinetics of the antigen in the presence of physiologically active solution the inventions can be shown to be distinct. Applicant respectfully traverses. Applicant respectfully submits that in this context Inventions II and III are so interrelated encompassing a process for the claimed product, that a search of both Inventions would not be burdensome. In an effort to facilitate prosecution however, claims to directed to Inventions II and III have been cancelled herein.



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Response Restriction/Election Requirement

## CONCLUSION

In conclusion, Applicant believes that the claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited. If the Examiner believes any informalities remain in the application, which may be corrected by Examiner's Amendment, whether any other issues can be resolved by telephone interview, telephone call with the undersigned attorney at (404) 745-2463 is courteously solicited.

Respectfully submitted,

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